IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of John Sefton	Group Art Unit: 1616
Serial No: 10/820,298	Confirmation No: 7456
Filed: April 7, 2004	Examiner: Badio, Barbara P
For: TAZAROTENE AND CORTICOSTEROID TREATMENT FOR PSORIASIS	

DECLARATION OF AN EXPERT REGARDING FACTS RELEVANT TO PATENTABILITY (37 C.F.R. § 1.132)

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

PURPOSE OF DECLARATION

1. This declaration is to establish evidence of patentability of one or more claims of the above referenced application.

2. The person making this declaration is an expert in the relevant art.

TESTIMONY OF EXPERT RELEVANT TO PATENTABILITY

3. Based upon the evidence in United States Patent Application Serial Number 10/820,298 and in H. Gollnick and A. Menter *British Journal of Dermatology* 1999; 140 (Suppl. 54): 18-23, there appears to be a general trend that combinations of tazarotene and corticosteroids increase efficacy in the treatment of psoriasis while reducing the adverse events as compared to tazarotene alone.

4. It is generally unexpected that a treatment would increase efficacy while reducing adverse events.

5. It is generally expected that administering two drugs to a patient will increase the adverse effects as compared to administering either of the individual drugs to the patient, where the dose of the individual drug is the same for individual and combination therapy.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.10
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE WITH SUFFICIENT POSTAGE AS EXPRESS MAIL (LABEL NO. EV295681885US IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, ALEXANDRIA, VA 22313-1450 ON FEBRUARY 8, 2005.
Printed name of person making deposit: Susan Bartholomew
Signature: Susan Bartholomew Date: FEBRUARY 8, 2005

6. Further, based upon the same evidence, there appears to be a trend of reduction in adverse events for the combination treatment of tazarotene and corticosteroid as the potency of the corticosteroid is increased.

7. It is generally expected that increasing the potency of a corticosteroid will increase the adverse events.

8. Finally, based upon said evidence, increased efficacy and reduced adverse events relative to 0.1% tazarotene gel treatment alone for the following combinations is observed: 0.1% tazarotene gel plus 0.1% mometasone furoate; 0.1% tazarotene gel plus 0.05% fluocinonide; 0.1% tazarotene gel plus 0.05% alclometasone dipropionate; and 0.1% tazarotene gel plus 0.1% betamethasone valerate. This combination of increased efficacy and reduced adverse events is unexpected.

TIME OF PRESENTATION OF THE DECLARATION

This declaration is submitted prior to final rejection.

DECLARATION

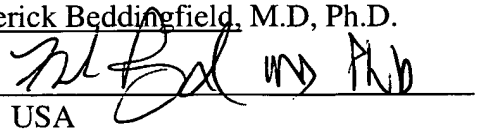
8. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on Information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

7. Expert in the Medical Art

Full name expert: Frederick Beddingfield, M.D, Ph.D.

Expert's signature:  Date: February 2, 2005

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